



Food and Drug Administration
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ERBE USA Incorporated
Mr. John Tartal
Director of Quality and Regulatory Affairs
2225 Northwest Parkway
Marietta, Georgia 30067

October 27, 2015

Re: K143306

Trade/Device Name: ERBE WaterJet Model ERBEJET[®] 2 System with HybridAPC Probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 28, 2015
Received: September 30, 2015

Dear Mr. Tartal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS)

regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.

For Director

Division of Surgical Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K143306

Device Name

ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe

Indications for Use (Describe)

ERBEJET® 2 System

The ERBEJET 2 is intended for lifting mucosal lesions by injection into the submucosa as well as the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME) in open as well as endoscopic surgery.

HybridAPC Probe

The HybridAPC probe is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope and for HF ablation of the mucosal lesion by Argon Plasma Coagulation (APC).

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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ERBE USA Incorporated
Traditional 510(k) for ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe

510(k) SUMMARY
[As Required by 21 CFR 807.92(c)]

Submitted By: ERBE USA, Inc.
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Contact Person: John Tartal
Director of Quality and Regulatory Affairs

Date Prepared: October 26, 2015

Trade (Proprietary) Name: ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe

Common Name: WaterJet Unit with Combination WaterJet and Argon Plasma Coagulation (APC) Probe

Classification Name and Code: Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400) and Jet Lavage (21 CFR Part 880.5475)

Product Code: GEI and FQH

Legally Marketed Predicate Device: ERBEJET® 2 System, 510(k) Number K072404
ERBELIFT™ Hand Pump and Flexible Probe, 510(k) Number K092090
ERBE Hybrid Knife™, 510(k) Number K083608
ERBE APC Integrated Filter Probes (FiAPC Probes) with Adaptor, 510(k) Number K060183

Note: The only change to the current ERBEJET 2 System is the addition of lifting mucosal lesions by injection into the submucosa in the Intended Use. There are no other changes to the current System being marketed in the U.S. Therefore, most of the information being provided is for the new device, HybridAPC Probe.

Device Description:

The HybridAPC Probe is used with the ERBE Water Jet Model ERBEJET 2 and an ERBE Argon Plasma Coagulator (APC) Model APC 2/ElectroSurgical Unit (ESU) VIO Model System. The Water Jet delivers pressurized sterile normal saline through the Probe to provide a saline cushion beneath mucosal lesions. The induction of the

ERBE USA Incorporated
Traditional 510(k) for ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe

saline into the submucosa is a routine practice and acts as a cushion which can reduce/limit unwanted tissue damage (penetration depth) when applying argon plasma coagulation. The APC/ESU System with the Probe supplies ionized (electrically charged) argon gas to create the HF argon plasma for the ablation of the lifted lesions. The HybridAPC Probe consists of tubing to the Water Jet, a cable with a filter integrated connector for the APC, and dual lumen tubing. The inside lumen delivers the pressurized sterile normal saline and the outer lumen delivers the electrically charged argon gas for the HF argon plasma. Clinicians would attach the Probe to the Water Jet and APC/ESU System. Then the Probe is positioned at the operative site under direct visualization endoscopically. If an operative endoscope is utilized, the working channel must be greater than 2.5 mm. Upon the setup of the Water Jet and APC/ESU System, the Probe is ready for use. The pedal of the ERBEJET 2 footswitch activates its water-jet capabilities. The tip of the Probe is placed against a lesion and the saline accumulates within the submucosal layer which cushions the lesion. Then the tip of the Probe is placed in close proximity of the raised lesion (not touching/non-contact modality). Finally, the footswitch for the APC/ESU System is depressed which delivers the ionized argon gas to create the HF argon plasma for the ablation of the lesion. The HybridAPC Probe's dimensional working parameters (tubing/tip interfacing with scope as applicable/tissue) are 2.3 mm Outer Diameter, 1.9 m Length. The device is manufactured with typical materials or agents used in the medical device industry such as tungsten, stainless steel, plastics, silicone, etc. The HybridAPC Probe is provided sterile and is single use.

Intended Use:

ERBEJET® 2 System - The ERBEJET 2 is intended for lifting mucosal lesions by injection into the submucosa as well as the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME) in open as well as endoscopic surgery.

HybridAPC Probe - The HybridAPC probe is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope and for HF ablation of the mucosal lesions by Argon Plasma Coagulation (APC).

Similarities and Differences of the Proposed Device to the Current Device (Predicate Comparison/Substantial Equivalence):

Similarities

1. The HybridAPC Probe (proposed device) is manufactured with the same materials as well as processes as the predicates HybridKnife and/or FiAPC Probes.
2. The proposed device is used in endoscopy like all of the predicate devices.

3. The HybridAPC Probe is a combination device that delivers pressurized sterile normal saline and electrical output to target tissue like the predicate HybridKnife.
4. The HybridAPC Probe with the ERBEJET 2 System has the capacity to lift mucosal lesions like the predicate ERBELIFT Hand Pump and Flexible Probe.
5. The addition of injecting into the submucosa to lift mucosal lesions in the intended use for the ERBEJET® 2 System and its inclusion in the intended use of the HybridAPC Probe is the same as the predicate ERBELIFT Hand Pump and Flexible Probe.
6. The proposed device has the same dimensions (2.3 mm Outer Diameter, 1.9 m Length) as the predicate, one of the FiAPC Probes.
7. The HybridAPC Probe has the same maximum electrical capacity (4,300 Vp) and maximum gas flow (2.4 Liters/Minute) as the predicate, one of the FiAPC Probes.
8. The proposed device's maximum wattage (80 watts) is within the range of the predicate FiAPC Probes.
9. The HybridAPC Probe is compatible with the same equipment (ERBEJET 2 System and/or Argon Plasma Coagulator (APC 2)/ElectroSurgical Unit (ESU Model VIO) and has the same operating principles as the HybridKnife in regards with delivering pressurized sterile normal saline to target tissue as well as the FiAPC Probes in regards to delivering argon plasma to target tissue.
10. The HybridAPC Probe is packaged in the same manner as the predicate, HybridKnife.
11. The proposed device is sterilized via Ethylene Oxide, single use, and disposable the same way as the predicate devices.
12. The HybridAPC Probe is manufactured by ERBE Elektromedizin GmbH like the predicate, HybridKnife.

Differences

1. Intended Uses
 - a. ERBEJET® 2 System
 - i. The intended use for the ERBEJET 2 has been modified to include "lifting mucosal lesions by injection into the submucosa". The ERBEJET 2 has been found to provide sufficient pressure to lift the submucosa.
 - b. HybridAPC Probe
 - i. The intended use is slightly different for the HybridAPC Probe in comparison to the FiAPC Probe in that upon the addition of lifting of mucosal lesions (via the injection of normal saline like the predicate ERBELIFT), "HF ablation of the mucosal lesions" by Argon Plasma Coagulation" for clarification purposes was added. This clarification is to inform the end user that raised/cushioned mucosal lesions are to be ablated. The association of the term ablation and coagulation

has been established for many years. See added Section 21, Clinical References (Note: This search was not exhaustive, but a sufficient list of literature demonstrating that lesions are ablated by argon plasma coagulation.).

Performance testing demonstrated that the ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe can lift mucosal lesions by injection of sterile normal saline into the submucosa and with a designated APC/ESU system ablate the lesion using argon plasma coagulation. Additionally, the proposed device (HybridAPC Probe) and predicate device (HybridKnife) were compared for functional equivalency in the lifting of the submucosa and ablation of three (3) different ex-vivo tissue types (esophagus, stomach, and rectum) from pigs. Testing of both devices was performed on each tissue type with and without submucosa lifting and then with coagulation. Testing was also done with minimum, default, and maximum intensity settings in triplicate (3X) for both devices. For the HybridAPC probe; the APC/ESU settings (using an ERBE APC 2/VIO 300 D) were Pulsed APC, Effect 2 at 20 Watts, 40 Watts, and 60 Watts, Argon Gas Flow 0.8 Liters/ Minute with a 2 mm distance (non-contact). For the Hybridknife; the settings (using an ERBE VIO 300 D) were Forced Coag, 60 Watts, Effect 1, 2, and 3 with tissue contact. The activation time for each was four (4) seconds. Then when lifting was employed, the ERBE WaterJet System was set to deliver at a 90° angle 3 ml of 0.9% NaCl. The study end point consists of macroscopic and histological examination of each tissue type upon coagulation per each designated setting in triplicate without and with lifting the submucosa for the proposed and predicate device. The acceptance criteria involved the macroscopic and histological data demonstrating that the proposed device (HybridAPC probe) is comparable or better than (substantially equivalent to) the predicate device (HybridKnife) in the mitigation of thermal tissue damage to the underlying tissue layers upon lifting the mucosa and coagulating/ablating tissue. The testing demonstrated when the tissues were analyzed macroscopically and histologically that the HybridAPC probe and HybridKnife produced comparable thermal effect when coagulating/ablating tissue. Also, the thermal damage profile and tissue effects were substantially equivalent in protecting the proper muscle layer upon the induction of 0.9% NaCl in the submucosa. Finally, both devices were also evaluated for producing the same submucosa lift on the 3 tissue types. The ERBE WaterJet System settings were Effect 40, 70, and 80 to deliver 2 ml, 3 ml, and 5 ml of 0.9% NaCl at an application angle of 90° into each specified tissue type in triplicate (3X) for the proposed and predicate devices. The study end point consists of macroscopic measurements for height and area of the created lift/ cushion per volume and injection (3X) in each tissue type upon the induction of 0.9% NaCl in the submucosa for the proposed and predicate device. The acceptance criteria involved demonstrating that the lifting/cushioning for the

HybridAPC probe was substantially equivalent to or better than the HybridKnife. The results of the test showed that height and area measurements of the created cushion upon the induction of 0.9% NaCl into the submucosa of the tissue types was comparable for the proposed and predicate devices.

2. The ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe is capable of delivering the sterile normal saline at a higher pressure (up to Effect 80 or 1,160 psi); than the predicate, ERBELIFT Hand Pump and Flexible Probe (up to 650 psi). Performance testing with the ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe at Effect 70 (1,015 psi, near the maximum setting) to lift the submucosa of esophageal tissue showed no detrimental damage to the tissue (i.e., no perforation) [Note: Fluid would travel the least path of resistance, that is within the submucosa.]. See Section 18, Performance Testing - Bench. The availability of having the capacity to deliver greater pressure to inject into the submucosa will allow clinicians the possibility to lift more difficult mucosal lesions. Additionally, there is more control of the pressurization (effects can be changed incrementally by 1 or 14.5 psi) with the ERBEJET 2 System than when using the ERBELIFT Hand Pump. Finally, in the instructions of the ERBEJET 2 and HybridAPC Probe the user is informed to use the lowest possible setting to achieve the desired tissue outcome.

FDA Recognized Safety Standards

ISO 14971, AAMI ANSI ISO 10933-1, IEC 60601-1, IEC 60601-1-2, AAMI ANSI IEC 62366, AAMI ANSI IEC 60601-2-2, IEC 60601-2-18, AAMI ANSI ISO 15223-1, AAMI ANSI ISO 11607-1, AAMI ANSI ISO 11607-2, ISO 11135, AAMI ANSI ISO 10993-7

Conclusion:

The ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe has the same principles of operation and technological characteristics as the predicate devices, ERBEJET 2 System, ERBELIFT Hand Pump and Flexible Probe, Hybrid Knife, and/or FiAPC Probes.

The ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe has been verified or validated in design control. ERBE Elektromedizin GmbH, in accordance with established procedures, directs and controls design activities. These procedures involve design and development planning, design input, design review, design verification/design output, design validation, design transfer, as well as design change control. The activities provide the oversight and forum for project approval, formal management/design review, evaluation, and final project approval. This work is documented within design review and the approvals are documented as part of the current change control system.

ERBE USA Incorporated
Traditional 510(k) for ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe

In addition to performance testing, the ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe was tested to “Recognized Consensus Standards”. Animal or clinical performance testing was not considered necessary.

All the changes with the proposed devices were verified or validated. As a result, the changes did not raise safety or efficacy concerns nor adversely affect safety or effectiveness. In conclusion, there are no issues with the ERBE WaterJet Model ERBEJET® 2 System with HybridAPC Probe that would raise additional safety or efficacy issues, when compared to the predicate devices.